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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,044	05/04/2001	Dusan Pavcnik	PA-5252-RFB	9073

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EXAMINER

STEWART, ALVIN J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/849,044	PAVCNIK ET AL.	
	Examiner	Art Unit	
	Alvin J Stewart	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 July 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babbs et al WO 98/25544.

Babbs et al discloses a stent graft comprising a stent (10) covered by a SIS sleeve (12). The stent has a proximal end and a distal end. The sleeve has a length about twice the length of the stent (see Fig. 2 and page 12, the last paragraph). The sleeve has a first portion within the inside surface of the stent and a second portion that is folded back over the proximal and distal end of the stent. The second portion extends from the proximal end to the distal end, along an outside surface of the stent (see Fig. 2). However, Babbs et al does not disclose that the first and second portions are secured to at least the distal end of the stent.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to secure the first and the second portions to the distal end of the stent because Applicant has not disclosed that the new limitations provide an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the leading and trailing end of the graft secured at the middle of the stent because no matter how the

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leading and trailing ends of the graft is secured, the final purpose of the implant is the same (biocompatibility).

Therefore, it would have been an obvious matter of design choice to modify Babbs reference to obtain the invention as specified in claims 1 and 7-9.

Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babbs et al WO 98/25544 in view of Douglas US Patent 6,090,128.

Babbs discloses the invention substantially as claimed. However, Babbs does not disclose a plurality of stents connected to each other.

Douglas teaches a plurality of stents connected to each other for the purpose of completely supporting the stent to the vessel wall (see col. 7, lines 56-58). Additionally, Douglas discloses stents having a frame comprising eyelets at the proximal and distal ends wherein the stents are connected to each other by biocompatible filaments.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to increase the number of stents in order to give completely support to the treatment area of the blood vessel.

Claims 1, 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregory US Patent 5,990,379 in view of Douglas US Patent 6,090,128.

Gregory discloses a stent graft comprising a stent (20) covered by an extracellular matrix layer (16). The stent has a proximal end and a distal end. The sleeve has a length about twice the length of the stent (see Figs. 8-10). The sleeve has a first portion within the inside surface of the stent and a second portion that is folded back over the proximal and distal end of the stent. The second portion extends from the proximal end to the distal end, along an outside surface of

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the stent (see Figs. 8-10 and col. 14, lines 31-36). However, Gregory does not disclose that the first and second portions are secured to at least the distal end of the stent and does not disclose a stent frame that has eyelets at the proximal and distal ends and a biocompatible filament that extends through the eyelets.

Douglas teaches a plurality of stents connected to each other for the purpose of completely supporting the stent to the vessel wall (see col. 7, lines 56-58). Additionally, Douglas discloses stents having a frame comprising eyelets at the proximal and distal ends wherein the stents are connected to each other by biocompatible filaments.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to increase the number of stents in order to give completely support to the treatment area of the blood vessel, as discloses by the Douglas reference.

Response to Arguments

Applicant's arguments filed June 04, 2004 have been fully considered but they are not persuasive.

Regarding the Babbs reference (mid-point connection), the Examiner does not agree with the Applicant's point of view. Nowhere in the Babbs reference discloses that the additional thickness of the stent graft will prevent the regular flow of the blood through the body. In contrast, the inner surface of any stent graft will permit the flow of blood therethrough without any problem. Figures 2 and 3b clearly show that the inner surface of the stent graft will permit the flow of blood without any problem.

Regarding the advantage of the Applicant's invention stating that the sleeve is folded back over a proximal end and distal end of the at least one stent, the Examiner still believes that

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the Applicant's representative has not disclose in the specification the importance of having the second portion of the sleeve folded back over a proximal end of the at least one stent and then along an outside surface of the at least one stent to the to the distal end thereof and secured in the distal end. Additionally, the Examiner believes that the Babbs reference will perform equally as well as the Applicant's stent graft. Therefore, the rejection maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 703-305-0277. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alvin J Stewart
Primary Examiner
Art Unit 3738

October 15, 2004.